MAY 10 2010

510(k) Summary of Safety and Effectiveness for the ADVIA® Chemistry Carbon Dioxide Liquid (CO2_L) Reagent

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

A. 510(k) Number: k100289

B. Date of Preparation: May 6, 2010

C. Proprietary and Established Names:
ADVIA® Chemistry Carbon Dioxide Liquid (CO2_L) Assay

D. Applicant

Contact: Sandra D. White, MS, RAC
Sr. Regulatory Technical Specialist

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E. Regulatory Information:

1. Regulation section:
   21 CFR §862.1160 Bicarbonate/carbon dioxide test system, (Enzymatic, Carbon Dioxide)
2. Classification:
   Class II
3. Product Code:
   KHS
4. Panel:
   75 – Chemistry

F. Predicate Device:

1. Device Name:
   Genzyme/DCL Carbon Dioxide L3K® Assay
2. Common Name:
   Carbon Dioxide-L3K Assay
3. 510(k) Number:
   k042362
4. Manufacturer:
   Genzyme Diagnostics P.E.I. Inc. (formerly Diagnostic Chemicals Limited)

G. Intended Use:

The ADVIA Chemistry Carbon Dioxide Liquid (CO2_L) assay is for *in vitro* diagnostic use in the quantitative determination of carbon dioxide in human serum and plasma on ADVIA Chemistry systems. Such measurements are used in the diagnosis and treatment of numerous potentially serious disorders associated with changes in body acid-base balance.

H. Device Description:

The ADVIA Chemistry Carbon Dioxide reagent is a solution containing buffer (pH 7.6 at 25^{0}C), 12.5 mmol/L PEP, ≥ 400 U/L PEPC (microbial), ≥ 4100 U/L malate dehydrogenase (mammalian), 0.6 mmol/L NADH analog, activators, stabilizers, a surfactant, and a preservative.

I. Test Principle:

The ADVIA® Chemistry Carbon Dioxide Liquid (CO2_L) Assay is based on enzymatic reactions. Phosphoenolpyruvate carboxylase (PEPC) catalyzes the first reaction which generates oxaloacetate. In the presence of MDH, the NADH analog is oxidized by oxaloacetate to NAD+ analog. The oxidation of NADH analog is measured by the decreased absorbance at 410/478 nm, which is proportional to the amount of CO2 in the sample.

J. Substantial Equivalence Information:

1. Predicate device name: Genzyme (formerly DCL) Carbon Dioxide - L3K Assay
2. Predicate K number: k042362
3. Comparison with predicate:

Similarities		
Item	**ADVIA Chemistry Carbon Dioxide Liquid (New Device)**	**Genzyme (formerly DCL) Carbon Dioxide L3K® Assay (Predicate Device)**
Intended Use	For the *in vitro* quantitative measurement of carbon dioxide concentration in serum and plasma.	Same
Sample Type	Serum and Plasma	Same
Test Principle	Enzymatic	
Reagents	A solution containing buffer, 12.5 mmol/L PEP, >400 U/L PEPC (microbial), >4100 U/L malate dehydrogenase (mammalian), 0.6 mmol/L NADH analog, activators, stabilizers, a surfactant, and a preservative.	Same
Format	Liquid, ready for use	Same
Reagent Storage Temperature	2-8°C	Same

Differences		
Item	**ADVIA Chemistry Carbon Dioxide Liquid (New Device)**	**Genzyme (formerly DCL) Carbon Dioxide L3K® Assay (Predicate Device)**
Measurement Wavelength	410 nm or 478 nm	405 nm or 415 nm
Calibrators	Siemens ADVIA Chemistry CO2 Calibrator/Diluent	Genzyme CO2 Calibrator
Calibration Frequency	Daily	The frequency of calibration, if necessary, using an automated system is dependent on the system and the parameters used.
Reportable range	10 to 40 mmol/L (mEq/L)	2.9 to 50.0 mmol/L (mEq/L)

K. Performance Characteristics

Substantial equivalence was demonstrated by testing several performance characteristics including imprecision, method comparison, interfering substances, serum/plasma equivalency, and analytical range. All of the evaluation studies gave acceptable results compared to the predicate device. These studies support that the ADVIA Chemistry Carbon Dioxide Liquid assay is substantially equivalent to the Genzyme Carbon Dioxide L3K® assay that is currently marketed.

I. Imprecision

Within run and Total Precision were established by assaying two control sera. Each sample was assayed 2 times per run, 2 runs per day, for at least 10 days. Precision estimates were computed according to CLSI document EP05-A2, *Evaluation of Precision Performance of Quantitative Measurement Methods*; Approved Guideline.

Sample	Mean mmol/L (mEq/L)	Standard Deviation mmol/L (mEq/L)	Coefficient of Variation %	N
Within Run Imprecision				
Level 1	16.1	0.19	1.2	40
Level 2	25.9	0.17	0.7	40
Level 3	34.6	0.33	1.0	40
Total Imprecision				
Level 1	16.1	0.56	3.5	40
Level 2	25.9	0.92	3.5	40
Level 3	34.6	1.21	3.5	40

II. Linearity/assay reportable range:

Linear/measuring range of the assay is 10-40 mmol/L (mEq/L). The low end of the assay range is calculated based on the Limit of Detection. The high end of the assay range is based on the linearity calculation.

III. Limit of detection

The estimations of the Limit of Blank (LoB) and Limit of Detection (LoD) were performed by running 40 replicates of 0.9% saline and 40 replicates of a Low Sample, using one lot of reagent. Data were obtained from a 10-day precision study. The LoD for the CO2 assays is <2mmol/L (mEq/L).

IV. Method comparison with predicate device:

The performance of this method (y) on a ADVIA 1650 was compared with performance of Genzyme carbon dioxide L3K® method (x) on a Hitachi 717. Sixty-two (62) serum samples tested ranging from 12.8 - 40.0 mmol/L (mEq/L) gave a correlation coefficient of 0.995. Linear regression analysis gave the following equation:
This method = 1.07 (predicate device) + 0.75 mmol/L (mEq/L).

V. Analytical specificity

Interferences from icterus, lipemia, and hemolysis were evaluated for this carbon dioxide method on an ADVIA 1650 analyzer using a significance criterion of >10% variance from the control. No significant lipemia interference was found at Intralipid levels from 0-500 mg/dL in a 22.2 mmol/L (mEq/L) carbon dioxide sample. No significant interference was found at unconjugated bilirubin levels from 0-25 mg/dL in a 21.7 mmol/L (mEq/L) carbon dioxide sample. Hemoglobin levels of 0-500 mg/dL were studied with acceptable results to a level of a 22.6 mmol/L (mEq/L) carbon dioxide sample. Bilirubin levels from 0-25 mg/dL in a 21.9 mmol/L (mEq/L) carbon dioxide sample was 10.3%.

L. Conclusion:

The ADVIA Chemistry Carbon Dioxide Liquid (CO2_L) assay is substantially equivalent to other products in commercial distribution intended for similar use. Most notably, it is substantially equivalent to the currently marketed Genzyme (formerly Diagnostics Chemicals Limited) Carbon Dioxide L3K® Assay (k042362).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food & Drug Administration
10903 New Hampshire Avenue
Building 66
Silver Spring, MD 20993

Siemens Healthcare Diagnostics
c/o Sandra D. White, Sr. Manager Regulatory Affairs
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Walpole, MA 02032

MAY 10 2010

Re: k100289
Trade Name: ADVIA Chemistry Systems Carbon Dioxide Liquid (CO2_L) Assay
Regulation Number: 21 CFR §862.1160
Regulation Name: Bicarbonate/carbon dioxide test system
Regulatory Class: Class II
Product Codes: KHS
Dated: April 1, 2010
Received: April 2, 2010

Dear Ms. White:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Courtney C. Harper, Ph.D.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indication for Use

510(k) Number (if known): k100289

Device Name: ADVIA® Chemistry Carbon Dioxide Liquid (CO2_L) Assay

Indication For Use:

For *in vitro* diagnostic use in the quantitative determination of carbon dioxide in human serum and plasma on ADVIA Chemistry Systems. Such measurements are used in the diagnosis and treatment of numerous potentially serious disorders associated with changes in body acid-base balance.

Prescription Use X (21 CFR Part 801 Subpart D) And/Or Over the Counter Use ____. (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K100289